



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor : Wenda C. Carlyle

Appln. No.: 09/014,087

Filed : January 27, 1998

For : PROSTHESES WITH ASSOCIATED
GROWTH FACTORS

Docket No.: S16.12-0062

Group Art Unit: 3738

Examiner: Paul B. Prebilic

REPLY BRIEF FOR APPELLANT

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5 DAY OF June, 2006.
Hallie A. Finucane
PATENT ATTORNEY

Dear Sir:

This Reply Brief is presented in response to the Examiner's Answer mailed on April 5, 2006 and in support of the Notice of Appeal filed November 16, 2005, from the final rejection of claims 1, 2, 4-11, 14, 15, and 21-28 of the above-identified application, as set forth in the Office Action mailed June 16, 2005.

I. STATUS OF CLAIMS

I. Total number of claims in the application.

Claims in the application are: 1-29

II. Status of all the claims.

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|----|-------------------------------------|------------------------------|
| A. | Claims cancelled: | 3, 12, 13, 16-20 and 29 |
| B. | Claims withdrawn but not cancelled: | None |
| C. | Claims pending: | 1, 2, 4-11, 14, 15 and 21-28 |
| D. | Claims allowed: | None |
| E. | Claims rejected: | 1, 2, 4-11, 14, 15 and 21-28 |
| F. | Claims Objected to: | None |

III. Claims on appeal

The claims on appeal are: 1, 2, 4-11, 14, 15 and 21-28

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- AA. Whether claims 1, 2, 9, 14 and 21 are unpatentable over claims 1, 8, 10, 13, 15, 34, 35, and 38-40 of copending application number 09/186,810 under the judicially created doctrine of obviousness-type double patenting.
- A. Whether claims 25 and 28 are properly rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,308,641 ("Cahalan patent").
- B. Whether claims 25 and 26 are properly rejected under 35 U.S.C. §102(b) as being anticipated by or, alternatively, as being unpatentable under 35 U.S.C. §103(a) as being obvious over European Patent Application No. EP 0476983 ("Bayne application").
- C. Whether claims 1-2, 4-5, and 9-11 are properly rejected under 35 U.S.C. § 103(a) as being obvious over the Bayne application in view of U.S. Patent No. 5,631,011 ("Wadström patent").
- D. Whether claims 6-8, 14, 15, 21-24 and 27-28 are properly rejected under 35 U.S.C. § 103(a) as being obvious over the Bayne application and the Wadström patent in view of U.S. Patent No. 4,648,881 ("Carpentier patent").

III. ARGUMENT

A. The Examiner Erroneously Rejected Claims 25 and 28 Under 35 U.S.C. §102(b) as Being Anticipated by the Cahalan Patent.

The Examiner erroneously rejected claims 25 and 28 under 35 U.S.C. §102(b) as being anticipated by the Cahalan patent. To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Independent claim 25 defines the present invention as a prosthesis comprising crosslinked natural tissue having an exogenous polypeptide growth factor associated therewith. There is no disclosure in the Cahalan patent of a crosslinked natural tissue for association with an exogenous polypeptide growth factor.

Applicants disagree with the Examiner's unsupported allegation that "...once Calahan attaches polyalkylimine to the tissue, it becomes part of the tissue." (Page 7 of the Examiner's Answer). The Examiner has never provided any factual or scientific documentation to support this allegation. Further, when provided with the analogy that one would not consider a titanium plate inserted into a bone to be bone once the plate bonded to the bone, the Examiner ignored the argument to maintain the rejection. Just as one would not consider titanium to be bone, polyalkylimine cannot be considered a natural tissue just because it attaches to natural tissue.

Next, Applicants disagree that the substrate having a polyalkylimine spacer attached to the spacer is a natural tissue as claimed. Natural tissue is defined at page 7, lines 14-16 of the specification. Polyalkylimine is not a natural tissue in animal species. Again, Applicants have repeatedly addressed the fact that a substrate having a polyalkylimine spacer is not a natural tissue. The Examiner has provided no factual or

scientific documentation to support the allegation that polyalkylimine is considered a natural tissue.

Further, the Examiner is relying upon the unsupported allegation that the polyalkylimine spacer is natural tissue to support the anticipation rejection. In the Examiner's Answer, the Examiner stated "For this reason, at least the crosslinked polyalkylimine treated tissue is crosslinked, and thus, the claim language is fully met with this interpretation." However, the Examiner again fails to address the fact that polyalkylimine is **NOT** a natural tissue, as claimed.

Further, Applicants cited portions of the Cahalan patent to support their position that the polyalkylimine spacer, not the substrate, is lightly crosslinked with glutaraldehyde. The Examiner alleges that the cited portions of the Cahalan patent are an admission that supports the Examiner's anticipation rejection. However, since polyalkylimine is not a natural tissue, the fact that a non-native spacer is crosslinked supports the Applicants' argument.

Further, Applicants question the Examiner's allegation that a claim element of crosslinked natural tissue may not have any patentable weight. (Examiner's Answer, pages 7-8). Applicants defined the present invention in claim 25 as a prosthesis that includes as an element crosslinked natural tissue as a substrate. The claim element must be given weight as the Examiner cannot pick and choose which elements of a claim are relevant in making an anticipation rejection. All claim elements must be met for an anticipation rejection.

The Examiner then argues in the alternative that even if the substrate with a lightly crosslinked polyalkylimine spacer does not anticipate the claim element of a crosslinked natural tissue (which it does not), then the Examiner alleges that the crosslinking of the non-native spacer would also inherently crosslink the tissue protein to some extent. To allege inherency, the Examiner must meet the burden of proof that what is asserted must necessarily happen. See M.P.E.P. § 2112.

In fact, the Examiner has ignored the case law and supporting scientific documentation provided as Exhibit A of Appendix B during prosecution and attached to the Amended Brief that states that the crosslinking of collagen with glutaraldehyde requires several hours, and not minutes as disclosed in the Cahalan patent. The

Examiner has repeatedly ignored this scientific evidence since it was first submitted on August 23, 2001 to maintain the rejection of claim 25 based upon inherency.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed Cir. 1999). "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). (Emphasis added). Yet when presented with this case law and scientific evidence contrary to the Examiner's allegation, the Examiner ignored and erroneously maintained the inherency rejection for about five years. Further, the Examiner has not provided any documentation in support of his assertion.

Finally, the Examiner makes the argument, for the first time in the Answer and after almost eight years of prosecution, that the claim term "associated" can mean that materials are merely next to each other. (Page 8 of Examiner's Answer). However, it should be noted that the polypeptide growth factor in the Cahalan patent is not next to the crosslinked natural tissue as claimed. Rather, the polypeptide growth factor is next to or associated with the spacer which separates and is positioned between the polypeptide growth factor and the substrate. Therefore, the Cahalan patent does not disclose a polypeptide growth factor associated with a crosslinked natural tissue as claimed.

The Examiner erred in rejecting claims 25 and 28 as being anticipated by the Cahalan patent. Applicants respectfully request that the Board overturn the anticipation rejections of claims 25 and claim 28 based upon the Cahalan patent.

B. The Examiner Erroneously Rejected Claims 25 and 26 as being Anticipated, or Alternatively, Made Obvious by the Bayne Application and Erroneously Rejected Claims 27 and 28 as being Made Obvious by the Combination of the Bayne Application and the Wadström Patent in view of Carpentier.

The Examiner erroneously rejected independent claims 25 and 26 as being anticipated by the Bayne application. However, the mere fact that all of the elements of a claim are present in a single reference does not necessarily make the reference an anticipatory reference.

"The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Examiner's reasoning for alleging that claim 25 is anticipated by the Bayne application is: "...since Bayne has all the claim features, as explained in the rejection, the Examiner maintains that the claims are anticipated thereby." (Page 9 of the Examiner's Answer). The Examiner's reasoning is contrary to case law. Therefore, the anticipation rejection is erroneous and is respectfully requested to be overturn.

The Examiner also erroneously rejected claims 25 and 26 as being obvious in view of the Bayne application. The Examiner is erroneously attempting to combine a method of treating natural tissue, such as fixed umbilical cord, with a method of treating an artificial support as disclosed in the Bayne application by erroneously alleging that (1) Applicants ignored lines 20-26 of page 8 of the Bayne application and (2) a tubular support as disclosed in the Bayne application includes fixed umbilical cord.

First, Applicants did not ignore lines 20-26 of page 8 of the Bayne application. See pages 10-11 of the Appeal Brief. Applicants addressed lines 20-26 of page 8 as being directed to a method of preparing an artificial implant such as a vessel. However, a method of preparing an artificial vessel does not affect the patentability of a claim directed to a crosslinked natural tissue. Therefore, the Examiner's statement that Applicants ignored lines 20-26 on page 8 is in error.

Second, the Examiner fails to address the fact that the Bayne application discloses two separate procedures for preparing a natural tissue and an artificial implant. Instead, the Examiner attempts to link the two distinctly separate procedures by alleging that fixed umbilical cord is a tubular support. Regardless of the form of the implant, the Bayne application addresses tubular supports in the method of preparing

an artificial implant. (See lines 20-26 on page 8) and addresses natural tissue by another method. The terminology in the Bayne application clearly indicates that Bayne considered a tubular support to be an artificial support and a natural tissue to be something other than an artificial tubular support, otherwise common terminology would have been used throughout the paragraph in question.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). (Emphasis added). Applicants submit that the Examiner used the language of claim 25 as a roadmap to combine aspects of two separate preparation procedures disclosed in the Bayne application for implanting two dissimilar materials, a natural vessel and an artificial vessel.

There is no teaching or suggestion to combine a method of preparing an **artificial** vessel with a method of preparing a **natural** tissue, absent the present invention, which is impermissible. Therefore, the Examiner erred in rejecting claims 25 and 26 as being obvious over the Bayne application.

Claims 27 and 28 include all of the limitations of claim 25, and recites additional features which further distinguish it from the cited references. Therefore, the Examiner erred in rejecting claim 27 and 28 as being obvious over the Bayne application and the Wadström patent and further in view of the Carpentier patent.

C. The Examiner Erroneously Rejected Claims 1-2, 4-5, and 9-11 under 35 U.S.C. § 103(a) as being Unpatentable over the Bayne Application in view of the Wadström Patent and Erroneously Rejected Claims 6-8 under 35 U.S.C. § 103(a) as being Unpatentable over the Combination of the Bayne Application and the Wadström Patent in view of the Carpentier Patent.

In the Answer, the Examiner ignores the fact that absent the present invention defined in claim 1, there is no teaching or suggestion to combine the Bayne application with Wadström Patent. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). (Emphasis added). Applicants submit that the Examiner used the language of claim 1 as a roadmap to combine the Bayne application with the Wadström Patent.

The Examiner has not explained how the use of fibrin can be incorporated into the procedure for a natural tissue as disclosed in the Bayne application. The Bayne application only discloses coating an artificial vessel with fibrin. (See page 8, line 22). However, an artificial vessel is not an allograft or xenograft tissue as defined in claim 1. Therefore, the combination of the Bayne application with the Wadström patent is not proper and the Examiner erred in rejecting claim 1 as being obvious.

Because the Examiner erred in rejecting claim 1, the Examiner's rejection of claims 2, 4-5, and 9-11 as being obvious over the Bayne application in view of the Wadström patent and claims 6-8 as being obvious over the Bayne application and the Wadström patent in view of the Carpentier patent are also improper.

D. The Examiner Erroneously Rejected Claims 14, 15 and 21-24 under 35 U.S.C. § 103(a) as being unpatentable over the Combination of the Bayne Application and the Wadström Patent in view of the Carpentier Patent.

The Examiner erroneously rejected claims 14, 15 and 21-24 under 35 U.S.C. § 103(a) as being unpatentable over the combination of the Bayne application and the Wadström patent in view of the Carpentier patent. Again, the Examiner improperly modified the Bayne application to combine mutually exclusive methods of preparing a **natural** tissue for implantation with the method for preparing an **artificial** vessel for implantation as previously discussed above with respect to independent claims 1 and 25.

The Carpentier patent discloses many different **natural** tissues that can be used as heart valve prostheses. (Emphasis added). There is no reason to combine the tissues disclosed in the Carpentier patent with the mutually exclusive method of preparation disclosed the Bayne Application for an artificial substrate. The combination of the Bayne application with the Carpentier patent would not provide a prosthetic heart valve comprising a substrate associated with VEGF as claimed in claim 14. Therefore, the Bayne application in view of the Wadström patent and the Carpentier patent does not make claim 14 obvious.

Applicants will consider filing a terminal disclaimer in the event that co-ending application Serial No. 09/186,810 issues into a patent. Therefore, the provisional double patenting rejection is moot.

Conclusion

Appellants respectfully submit that claims 1-2, 4-11, 14-15, and 21-28 are patentable over the cited prior art. It is respectfully requested that the rejections be reversed, and that all pending claims 1-2, 4-11, 14-15 and 21-28 be allowed.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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